

NOV 30 2006

Attorney Reference No.: 59486.000002

Application No. 09/853,635

Filed: May 14, 2001

Applicant: Bengt Krister OLSON

Group Art Unit: 1655

Examiner: Dr. Kailash C. Srivastava

Date of Amendment: November 30, 2006

REMARKS**Claim Amendments**

Applicant amended claims 1, 111, 118 and 119. Applicant added new claims 134-137.

Support for the claim amendments and new claims is found in the specification, considered as a whole, including original claims, e.g., at page 14, lines 1-10 and 24-28, and page 16, lines 4-16.

General Matters

The Examiner suggested the inclusion of certain Application identifying information in the header of this paper. Applicant appreciates and followed the suggestion.

Restriction/Election

Applicant's election with traverse of Group I was acknowledged and entered, but the restriction requirement was made final. Office Action, pages 2-3. Applicant continues to traverse the restriction requirement for all the reasons set forth in the Amendment and Reply to Office Action filed on December 28, 2005, which reasons are incorporated herein by reference.

It was suggested to Applicant that the non-elected claims be canceled in a response to the Office Action. Office action, page 3. Applicant appreciates that suggestion but would like to defer the decision regarding cancellation of the non-elected claims until an indication of allowance of elected claims.

Applicant notes a minor informality that has been corrected in the Office Action. In the March 28, 2006 restriction requirement, Group I was identified as including claims 106, 108 - 115, 117, 120, 124-127 and 129-131. All of those claims were dependent from claim 104, and thus claim 104 was implicitly included in Group I. Applicant appreciates the

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Examiner's correction of that informality by confirming that claim 104 was included in the Group I, elected for prosecution.

Objection to Specification

The specification was objected to because the application did not properly cite the application priority data and Applicant was advised to amend the specification to include a reference to the Danish application from which this application claims priority. Office Action, page 4.

Applicant appreciates the Examiner's suggestion and has amended the application accordingly.

The specification was said to be replete with terms, which are not clear concise and exact. As examples were cited the passage at page 7, lines 34-35 and at page 5, line 24. Office Action, page 4.

With respect to the objection to the term "Grape seed of *Vitis vinifera*" (page 7, lines 34-35). Applicant does not agree with this objection. It is known in the art that the term "grape" includes, among others, both grapevines and grapes which are useful for human consumption.

Vitis Vinifera is the name of one species of grapevines which is also known as the European Grapevine. However, other species of grapevines exist (see <http://en.wikipedia.org/wiki/Grape>). Furthermore, there exist a large number of varieties of grapevines; many of which are cultivars of *Vitis vinifera*. Accordingly, Applicant respectfully requests reconsideration of this objection.

With respect to the objection at page 5, lines 33-35, regarding "the tomato variety which is..." Applicant amended the specification to correct the minor informality noted by the Examiner.

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Applicant is unaware of any additional minor errors in the specification. If the US Patent and Trademark Office becomes aware of such errors, Applicant would appreciate a notification regarding same.

Claim Objections

Claim 104 was objected to because for each one of glycosaminoglycan and polyphenolic, hydrophilic antioxidant, recited in the claim, such components are either synthetic or those obtained from cartilage and enzymatic hydrolysis and grape seed, respectively. It was inquired how one would differentiate a given synthetic component/compound from the counterpart of that compound obtained from a natural source. Office Action, page 5.

Applicant respectfully submits that a person of ordinary skill in the art would be readily able to differentiate between such components which are synthetic or obtained from a natural source because methods for differentiation of such components are known.

It was suggested that in claim 111, the word "claim" should be inserted after the word "to". Applicant followed this helpful suggestion and amended claim 111 accordingly.

Claim Rejections under 35 USC Section 103

Claims 104, 106, 108-115, 117, 120, 124-127 and 129-131 were rejected as obvious over the combined teachings of Kosbab (WO 00/07607) in view of Bombardelli et al. (EP, 0,659, 402) ("Bombardelli") and Hersh (U. S. Patent 5, 906, 811).

It was stated that claims "...recite a method to enhance or maintain the collagen synthesis in the dermis comprising orally administering a composition comprising: glycosaminoglycan obtained from cartilage enzymatic hydrolysate or synthetically produced (ii) hydrophilic antioxidant present in grape seed extract or synthetically obtained, and lycopene." It was also asserted that the composition further comprises: *Acerola* extract and beta-carotene. Office Action, page 5.

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Initially, Applicant respectfully submits that an Acerola extract and beta-carotene are recited in dependent claims 117 and 113, but not in independent claim 104. Thus, it is improper to implicitly limit claim 104 to the inclusion of the Acerola extract and beta-carotene. Applicant wishes to point out that claim 104 is also directed to lessening the decrease in collagen synthesis.

Applicant respectfully traverses the obviousness rejection of the aforementioned claims for the reasons detailed below.

At the outset, it is respectfully pointed out that the initial burden of establishing a basis for denying patentability to Applicants claimed invention rests on the United States Patent and Trademark Office ("Patent Office"). *In re Fine*, 5 USPQ2d 1596 (CAFC1988).

It is further submitted that a proper obviousness rejection can be made only if there is some teaching, suggestion or motivation provided by the prior art to combine the teachings of the prior art. This standard has also been rephrased as a direction to the Patent Office to determine whether "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains". *Dystar Textilfarben GMBH & CO Deutschland KG v C.H. Patrick CO., and Bann Quimica LTDA*, CAFC Appeal No. 06-1088, p. 6 (decided October 3, 2006).

As stated by the Federal Circuit in *Dystar*, it must be considered whether a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and whether there would have been a reasonable expectation of success in doing so. *Id*

According to the Office Action, "Kosbab teaches a method to enhance collagen production in an individual via administering a composition comprising cartilage extract (bovine and shark cartilage) or glycosaminoglycan = chondroitin sulphate (Page 24, Line 6) and antioxidant containing plant extracts (See e.g., Page 8, Lines 3-4), wherein antioxidants

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are: carotenoid and flavonoids. The sources for carotenoids in said composition are β -carotene, lutein, lycopene, zeaxanthin (Page 24, Lines 24-25) and sources for flavonoids are: extracts of grape seed (Page 23, Lines 26-32 and Page 24, Lines 10 and 20-21)." Office Action, pages 5-6.

Applicant respectfully disagrees with this characterization of Kosbab. Kosbab is directed to cancer protective and therapeutic compositions as well as to protective and therapeutic formulas for the treatment of osteoporosis. *See*, e.g., page 2, lines 25-28 and page 4, lines 6- 8. According to Kosbab, the multi-component compositions of his invention are based on recognition that cancer is the result of the multi-factor etiology requiring utilization of multiple biochemical factors to successfully ameliorate or reverse conditions or symptoms of cancer. Page 1, lines 29 - 32.

To that end, Kasbob's cancer protective and therapeutic compositions combine components which control oxidative stress, provide for appropriate neovascular regulation, provide factors necessary for stimulation or promotion of collagen maintenance and synthesis and tissue restoration. Preferred combinations of anti-oxidants and neovascular regulators include combinations of a plant extract providing antioxidant effect comprising bioflavanoids with a neovascular regulator selected from the group of genistein, daidzein, soy isolate and cartilage or preferably chondroitin sulphate. Page 2, lines 28-32.

Kosbab's preferred compositions include a number of ingredients having various functionalities, such as two or more antioxidant components, two or more neovascular regulators, a component that stimulates or enhances collagen synthesis, a component that regulates blood lipid levels, a component that stimulate the body's immune response, a component that regulates blood glucose levels and mineral, vitamin and cofactor components to supplement deficiencies and help maintain and restore normal cell biochemistry. *See*, page 3, lines 26-line 31.

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Applicant strongly disagrees with the assertion in the Office Action that Kosbab discloses "a method to enhance collagen production in an individual via administering a composition comprising cartilage extract (bovine and shark cartilage) or glycosaminoglycan = chondroitin sulphate (page 24, line 6) and antioxidant containing plant extracts (see e.g. page 8, lines 3-4), wherein the antioxidants are carotenoid and flavonoids". Office Action, page 5. Applicant also traverses the assertion that sources of the carotenoids in said composition may e.g. be β -carotene, lycopene (page 24, lines 24-25) and sources for flavonoids are: extracts of grape seed (page 23, lines 26-32 and page 24, lines 10 and 20-21). *Id.* at page 6.

At page 24, line 6, Kosbab discloses chondroitin sulfate or cartilage in Formula I, which comprises a number of other ingredients. At page 8, lines 3-4, Kosbab discloses different sources of bioflavanoids, including bilberry, grape seed extract, Ginkgo biloba, pine bark extract, green tea extract and individual bioflavanoids described in the preceding portion of Kosbab's description.

There is absolutely no suggestion within the four corners of Kosbab's disclosure or in any other prior art of record, that Kosbab's Formula I is utilized to increase collagen production and Kosbab also fails to disclose or suggest that his Formula I needs to be modified to include carotenoid and flavanoids as anti-oxidants. Formula I lists antioxidant vitamins, e.g., Vitamin C and/or Vitamin E. See Kosbab, page 24, line 1. Significantly, Formula I at page 24, is directed to a specific cancer preventative and therapeutic formula, while the disclosure at page 8 is a general disclosure relating to antioxidants. Kosbab provides no motivation to substitute anti-oxidants of Formula I with those of his page 8, particularly since his Formula I identifies particular anti-oxidants he wishes to use.

At page 24, lines 24-25 Kosbab discloses Formula III which includes grape seed extract, lycopene and genistein and chondroitin sulphate, and a number of other ingredients. Formula III is also a specific cancer preventative and therapeutic formula, which is not

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indicated for increasing collagen production. Formula III would have failed to suggest to persons of ordinary skill in the art Applicant's claimed invention at least because the Formula is not suggested by Kolbab for increasing collagen production or the decrease in collagen synthesis in the dermis and because it explicitly states that lycopene is not used for that purpose. See Table 2, at page 32.

It was additionally stated that Kosbab teaches collagen maintenance (Table 2) with a composition comprising shark cartilage, grape seed extract and lycopene. Office Action, page 6.

It is unclear which portion of the Kosbab's disclosure is referred to in connection with this assertion. Nonetheless, it appears that the assertion may be based partially on Table 2 and Formulae I, II and III. Applicant respectfully submits that the selective picking and choosing of isolated portions of Kosbab's disclosure and combination thereof, without suggestion or motivation provided by Kosbab himself, is improper as a matter of law. See, e.g. *Arkie Lures v. Larew Tackle*, 119 F.3d 953 (Fed.Cir. 1997). In *Arkie Lures*, the Larew invention was directed to a "salt-impregnated plastisol fishing lure." Prior art had disclosed salty bait to catch fish, plastisol lures and the use of organic fish attractants in plastic lures. No reference showed or suggested a plastisol salty lure. In that case, the CAFC overturned the district court's finding of obviousness.

The court stated:

No prior art showed or suggested the combination of a plastisol lure with salt, although the prior art was extensive as to the separate elements, and suggested including organic attractants in plastic lures....The question is not whether salt "could be used," as the district court concluded, but whether it was obvious to do so in light of all the relevant factors....*It is insufficient to establish obviousness that the separate elements of the invention existed in the prior art, absent some teaching or suggestion, in the prior art, to combine the elements.* Indeed, the years of use of salty bait and of plastic lures, without combining their properties, weighs on the

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side of unobviousness of the combination.

Id. at pages 957 and 958 (Emphasis added).

Similarly, Kosbab describes some, but not all, components, of Applicant's claimed invention in disparate portions of his disclosure, but fails to suggest the combination of such components to provide a method of increasing collagen synthesis or lessening the decrease in collagen synthesis in the dermis by the oral administration of Applicant's claimed composition. As discussed above, Formulae I, II and III are directed to prevention of cancer and treatment of cancer, which do not suggest Applicant's method.

The lack of suggestion to provide Applicant's method in Kosbab is underscored by the fact that lycopene is not identified by Kosbab to have properties of increasing collagen synthesis or lessening the decrease in collagen synthesis. In Table 2, at page 32, lycopene is identified as having five different properties: antioxidant to control oxidative stress, regulate blood lipid levels and lipoprotein (A) regulation, supplement deficiencies, regulation and inhibition of homocysteine, and anti-tumor/anti-cancer effect. While Formula III contains nine different categories of ingredients, comprising a total of approximately thirty-five different specific compounds or categories, some of which include grape seed extract, lycopene and chondroitin sulfate, Formula III is specified by Kosbab to be used for cancer prevention and cancer therapy.

The lack of the *prima facie* case of obviousness based on Kosbab is buttressed by the fact that in Table 2, there are at least 18 different ingredients having, according to Kosbab, collagen maintenance or collagen synthesis function, but lycopene is not one of them. As discussed above, all such ingredients are disclosed within the context of "Cancer Formulations", see page 32. Thus, Kosbab teaches away from Applicant's claimed invention of claim 104. See, *Jansen v. Rexall Sundown Inc.*, 68 USPQ2d 1154 (CAFC 2003). (The court held that a patent claim directed to a method of treating or preventing pernicious anemia comprising administering to a human in need thereof a combination of

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vitamin B₁₂ and folic acid was not infringed by administering the claimed vitamins in the claimed doses for a purpose other than treating or preventing pernicious anemia, at least because such a person would not have an intent to treat the pernicious anemia.) To paraphrase a well established rule (that which anticipates if earlier in time, infringes if later), Kosbab's disclosure, specifying lycopene as an ingredient not useful in collagen synthesis or lessening the decrease thereof, would have failed to render obvious Applicant's claim 104.

Bombardelli et al., EP 0 659 402 A2 was alleged in the Office Action to teach a composition comprising hydrophilic antioxidants with lycopene "... wherein the sources for hydrophilic antioxidants are: proanthocyanidin a procyanidole oligomers extracted from *Vitis vinifera*. Said composition also comprises β -carotene, lycopene and vitamin E wherein tomato is the source of lycopene (Page 6, Lines 47-53 and Page 7, Lines 1-4). Thus, Bombardelli et al. clearly define the sources of hydrophilic antioxidants and lycopene in their composition and further teach that the sources for lycopene and hydrophylic antioxidants comprising their composition are natural." Office Action, page 6.

Applicants respectfully traverse this assertion. Bombardelli fails to disclose a composition comprising glycosaminoglycan, and fails to suggest or disclose any effect of his composition on increasing collagen synthesis or lessening the decrease in collagen synthesis. Bombardelli teaches that his composition can be used in the prevention of physiopatological conditions related at least partially to overproduction of free radicals, particularly aging, atherosclerosis and cancer. *See*, Abstract. There is no suggestion in Bombardelli or in Kosbab to combine any particular portion of Bombardelli with Kosbab. The combination of portions of Bombardelli's disclosure with Kosbab could only be made with the benefit of hindsight provided by Applicant's disclosure, which is impermissible in non-obviousness analysis.

It was stated in the Office Action that:

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Hersh teaches a method to orally administer the same composition as that elucidated by Kosbab et al. Thus, Hersh intrinsically teaches a method to enhance collagen synthesis/maintenance in an individual because Hersh teaches to administer a composition according to the same steps and comprised of same compositions as those instantly claimed. Thus, both Kosbab and Hersh teach a method to enhance/maintain collagen synthesis via orally administering to an individual in need thereof a composition comprising same components and according to the same steps as are claimed in the instant method invention.

Office Action, page 6.

Applicant respectfully traverses this assertion. Applicant respectfully submits that Hersh is not analogous art. To support a proper rejection under 35 U.S.C. § 103, the reference must be in the same field of endeavor as Applicants' claimed invention. The MPEP states, "TO RELY ON A REFERENCE UNDER 35 U.S.C. 103, IT MUST BE ANALOGOUS ART." MPEP § 2141.01(a). Quoting *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992), the MPEP further states:

"In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *Id.*

Hersh is not in the field of Applicant's endeavor at least because his disclosure is directed to intra-oral antioxidant preparations used to prevent and ameliorate signs and symptoms and complications to oro-pharyngeal cavity and mouth from damage caused by free radicals species induced by tobacco smoke, smokeless tobacco or similar products. See column 1, lines 5-18. This is a different field of endeavor than Applicant's method for increasing collagen synthesis or lessening the decrease in collagen synthesis in the dermis. Hersh's disclosure is also not pertinent to the particular problem addressed by Applicant, i.e., lessening the decrease in collagen synthesis or increasing collagen synthesis in the dermis.

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Furthermore, Hersh fails to teach or suggest that his composition includes glycosaminoglycan, required by Applicant's claims.

For at least these reasons, Hersh cannot be properly combined with Kosbab or Bombardelli and the assertion that Hersh intrinsically teaches Applicant's method of enhancing collagen synthesis is not supported by Hersh's disclosure.

Even if, *arguendo*, *prima facie* obviousness of the claimed invention were established, Applicant provided evidence establishing unexpected properties of the claimed invention, which rebut the alleged obviousness determination. Applicant demonstrated that the combination of cartilage extract (F), grape seed extract (G) and tomato extract (T) synergistically increases collagen synthesis compared to the individual compounds (see Applicant's specification, Table 2 on page 20). Table 2 shows that cartilage extract (F) alone gives a 30% increase in collagen synthesis as measured by the degree of proline incorporation. Combining cartilage extract (F) with either grape seed extract (G) or tomato extract (T) results in a lesser degree of collagen synthesis than the use of cartilage extract (F) alone. Moreover, the combination of grape seed extract (G) and tomato extract (T) results in a 20% decrease in collagen synthesis relative to control. Thus, it is surprising and unexpected that the combination of all three components (FGT) gives 80% increase in collagen synthesis since both T and G diminish the effect of F alone and together they have a negative effect on the collagen synthesis.

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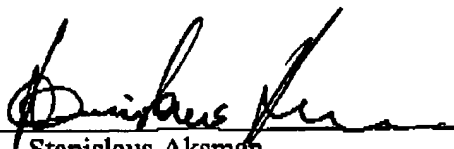
Conclusion

Applicant respectfully submits that for all of the reasons set forth above, the invention of claim 104 is *prima facie* patentable in view of Kosbab, Bombardelli and Hersh. Since all of the remaining rejected claims depend from claim 104, Applicant respectfully requests withdrawal of obviousness rejections of all of the claims and an indication of allowance thereof. Further, claims dependent from Claim 104 also contain additional recitations, and deserve separate patentability consideration.

In the event that any outstanding issues remain, Applicant respectfully requests the courtesy of a telephone call to the undersigned counsel to resolve such issues in an expeditious manner and place the application in condition for allowance.

In the event that any variance exists between the fees enclosed herewith and those deemed necessary by the US Patent and Trademark Office to enter and consider this amendment and response, or to maintain the present application pending, please credit or charge such variance to the undersigned deposit account number 50-2478.

Respectfully submitted,

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